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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 226,046	01 05 1999	STEVEN M. REPPERT	10217 250003	1585

7500

06 17 2002

PAUL T CLARK
FISH & RICHARDSON
225 FRANKLIN STREET
BOSTON, MA 021102804

EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

3646

DATE MAILED: 06 17 2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/226,046

Applicant(s)
Reppert et al.

Examiner
Michael Pak

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 35, 53, 55, and 78-85 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 35, 53, 78, and 80-85 is/are rejected.
- 7) ☒ Claim(s) 55 and 79 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s): _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1 April 2002 (Paper No. 25) has been entered.

Response to Amendment

2. Applicant's response to office action filed 1 April 2002 (Paper No. 26) has been received.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments filed 1 April 2002 (Paper No. 26), have been fully considered but they are not found persuasive.

5. Applicant's note regarding errors in the advisory action is appreciated. Applicants note that a reply was filed June 27,

2001 which is the unentered amendment filed on 2 July 2001 (Paper No. 20). Applicant also note that the Notice of Appeal was filed by the applicant on 24 August 2001 which is the same paper filed on the file wrapper contents of the application as 27 August 2001 (Paper No. 21). It should be noted that any filing date indicated by the examiner is the date on the contents page of the application and not necessarily the mailing date of the paper.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 80-85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims recite or encompass the term "100 mg/ml denatured salmon sperm" which is new matter not disclosed in the specification on page 35. The specification discloses "100 ug/ml."

7. Claims 33, 35, 53, and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a genus of melatonin receptor because of the recitation of "high affinity melatonin receptor" without specific structure and recitation of "substantially identical" which does not limit the structural difference with the recited SEQ ID NO:. However, the essential feature of the invention is the specific human melatonin receptor consisting of SEQ ID NO: 12. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the only disclosure of a specific human melatonin receptor does not have written description for the genus of human melatonin receptor whose sequences cannot be envisioned.

Applicants argue that *University of California v. Eli Lilly and Co.* is drawn to cDNA and not methods. However, the essential feature of the method claim is using the specific human melatonin receptor consisting of SEQ ID NO:12 and thus the ability to envision the receptor is essential for the description of the claim.

Claim Rejections - 35 USC § 112, second paragraph

6. Claims 33, 35, 53, and 78 are rejected under 35 U.S.C. 112,

second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 35 recite or encompass the term "high affinity melatonin receptor" but the metes and bounds of the term is not clear. Applicant submitted a review article by Dubocovich et al. which is a post filing date reference. It was not clear from Dubocovich et al. whether the one skilled in the art at the time of the filing was able to differentiate the when a melatonin receptor was "high affinity" or another affinity receptor. The reference seems more retrospective from after the filing date and does not indicate whether at the time of the invention whether such terms clearly set forth the metes and bounds of when a receptor is high affinity melatonin receptor. Furthermore, page 182 of Dubocovich et al. teach that high affinity melatonin receptor has an affinity(KD?) of 30-300 pM but the figure 1 on page 183 indicate that MT3 which is the low affinity melatonin receptor is 300 pM- 2 nM which is confusing because it is not clear if you have a 300 pM melatonin receptor whether it is a high affinity or low affinity melatonin receptor.

Claim 53 and 78 recite or encompass the term "substantially identical" but the metes and bounds of the term is not clear. It is not clear when the melatonin receptor is substantially identical to SEQ ID NO:12 when it is not substantially identical.

9. No claims are allowed. Claims 55 and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims without precipitating further rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 303-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
13 June 2002